



DEPARTMENT OF HEALTH AND HUMAN SERVICES

34591d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

March 24, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 19

Cary A. Wetzstein
Chief Executive Officer
Quality Meats and Seafood, Inc.
700 N. Center Street
West Fargo, North Dakota 58078

Dear Mr. Wetzstein:

On January 12 and 14, 2004, we inspected your seafood processing facility located in West Fargo, North Dakota. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your smoked salmon is adulterated in that the vacuum packed smoked salmon has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or rendered injurious to health. You may find the Act and its implementing regulations through links in FDA's home page at www.fda.gov.

The deviations noted on the FDA-483, Inspectional Observations, of most concern are as follows:

You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not make nor record monitoring observations at the storage critical control point listed in your HACCP plan for fresh fish and ready-to eat seafood, specifically, vacuum packed Smoked Salmon.

Page Two

Cary A. Wetzstein
March 24, 2004

You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for vacuum packed Smoked Salmon does not list the food safety hazard of *Clostridium botulinum*.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and all implementing regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

For information regarding recommended control strategies for pathogen growth and toxin formation, please refer to the *FDA Fish and Fishery Products Hazards and Controls Guidance, Third Edition*, Chapter 12 (Pathogen Growth & Toxin Formation as a Result of Time/Temperature Abuse), found at <http://www.cfsan.fda.gov/~comm/haccp4.html>.

Please send your reply to Compliance Officer Tyra S. Wisecup at the address in the letterhead. If you have questions regarding any issue in this letter, please contact Compliance Officer Wisecup at (612) 758-7114.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

TSW/ccl

